

SUBJECT: J12-03 – Review of [REDACTED]  
Proposed “Scope of Work” for [REDACTED] Expert,  
[REDACTED]

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\*\*\*\*\* [REDACTED] \*\*\*\*\*

An assessment prepared by [REDACTED]  
[REDACTED] if written  
according to the directives in the Scope of Work submitted to Audrey Binder for  
review by EPA will be of limited value to the Agency in evaluation of the potential  
hazards of the J12-03 submission microorganism, [REDACTED]. The directives in that  
Scope of Work, for the most part, do not address the predominant issue which is  
the potential for increased incidence of disease if there is increased exposure to  
the microorganism.

As has been stated repeatedly over the last few months, the Agency  
[REDACTED]

[REDACTED]

Specific comments on each of the directives follow.

1. *Current incidence of [REDACTED] compared to other microorganisms known to cause [REDACTED] supported by data from research at [REDACTED] or through publications.*

This, perhaps, may be useful information if obtained from the scientific literature. However, the data/information, particularly if generated from university [REDACTED] laboratory statistics, need to be accompanied by a thorough description of exactly which microorganisms are routinely tested for in [REDACTED] labs, and an exact description of how a designation of a causal agent as [REDACTED] would be made.

Statistics from the Michigan State University may not be appropriate for the entire U.S., including its territories, since it well known from the literature that the incidence of [REDACTED] is greater in warm, humid climates as opposed to colder ones.

2. *Descriptions of other microorganism that are common causes of [REDACTED] including examples of microorganisms that thrive in similar conditions [REDACTED]. Please address microorganisms (corrected for spelling errors) on the following list:*

*Acetobacter aceti*

*Saccharomyces cerevisiae*

*Clostridium acetobutylicum*

*Escherichia coli* K12

*Bacillus licheniformis*

*Aspergillus niger*

*Aspergillus oryzae*

*Penicillium roqueforti*

*Bacillus subtilis*

*Saccharomyces uvarum* (whose currently valid name is *S. bayanus* var. *uvarum* - from recent phylogenetic analyses of the genus which has determined that *S. uvarum* does not warrant separate species status)

The first sentence of this directive may provide useful information and is somewhat a continuation of directive #1.

However, the evaluation of the ten microorganisms listed (which are the 10 eligible recipient microorganisms in our 5(h)4 Exemptions) will be of no use to the Agency as there is no relevance to the issues associated with J12-03. This exercise would be a waste of time and money.

*3. Descriptions of species and subspecies [REDACTED] that are common causes of [REDACTED], including a discussion of [REDACTED]. If known, the percentage of [REDACTED]. Specifically address literature in which [REDACTED] is discussed in trends, in terms of frequency of the disease.*

An analysis of the literature for the incidence of [REDACTED] will be of little value to the Agency. The Agency is aware that there are but a few articles in the literature in which the species [REDACTED]. However, there are numerous articles on the cause of [REDACTED]. In the absence of any further identification data which indicates that the recipient microorganism for [REDACTED] is something other than [REDACTED], a worst-case scenario using [REDACTED] will need to be used in the risk assessment.

*4. Assess the frequency with which [REDACTED] cases in the field are confirmed to be [REDACTED] using a genetic analysis to determine species, strain, and/or genotype. Assess the frequency with which only the genus [REDACTED] caused [REDACTED] is confirmed. Describe common methods used by [REDACTED] to identify [REDACTED] in [REDACTED].*

The information, as requested, is questionable. However, as requested in the response to directive #1, it would be useful to know exactly what microorganisms are tested for, and the implications if a sample of infected [REDACTED] is 'negative' for all of the microorganism looked for. What happens if a sample is returned with 'negative' for any [REDACTED] pathogens looked for? Do [REDACTED] then treat with antibiotics and see if the infection is eliminated? Do they treat the [REDACTED] with antifungals next – or even simultaneously with both antimicrobials? Is a private veterinarian called in to further test for the infectious agent? How does a determination of [REDACTED] (whatever species/genotype) ever get made in practice – in contrast to determinations that can be made in a research laboratory with capabilities for molecular analyses or other sophisticated methodology?

In addition, please have your expert address the potential for misidentification of a causal agent of [REDACTED] as something other than [REDACTED]. In a review article of [REDACTED], [REDACTED] stated that the real incidence of [REDACTED] caused by [REDACTED] is probably much higher than that reported in the literature because of the potential for misidentification of the organism as a yeast, and because of its failure to grow

under routine microbiological conditions. [REDACTED] is usually outgrown on plates by bacteria and fungi, so selection media for [REDACTED]

5. Describe how [REDACTED] caused by [REDACTED] is resolved with and without medical intervention. Discuss practices by the [REDACTED] for resolving the disease, such as allowing the animal to self-resolve the infection, treatability of [REDACTED] caused by [REDACTED], re-occurrence, permanent impairment of the [REDACTED] information that leads to a decision to cull infected [REDACTED], and frequency with which culling occurs.

The requested information may be useful if it is something not already gathered by the Agency from the scientific literature on [REDACTED] infections. Perhaps, there have been recent developments in advanced antifungal agents or in [REDACTED] used to treat [REDACTED] infections or used as prophylactic measures? In brief, the literature suggests that [REDACTED] infections are difficult to eliminate, that the antifungal treatments used are cost-prohibitive, that [REDACTED] rarely resumes to normal levels due to irreversible damage to the [REDACTED], etc. Information to the contrary would be valuable to the Agency if such literature exists.

6. Recent data on the economic loss to the [REDACTED] industry due to [REDACTED], including data for [REDACTED] as a whole as well as [REDACTED] caused by [REDACTED].

Current estimates, in addition to the two the Agency has already obtained, of economic losses to the [REDACTED] industry in the U.S. due to [REDACTED] would be useful.

7. Conditions in [REDACTED] that give rise to [REDACTED] caused by [REDACTED] the likelihood of [REDACTED] to be spread between [REDACTED]. Methods to treat equipment and/or control the environment in order to minimize [REDACTED] in [REDACTED].

Information on the spread of [REDACTED] organisms between [REDACTED] through either environmental exposure or through contaminated [REDACTED] equipment may be useful to the Agency. The effectiveness of the disinfectants used on [REDACTED] equipment and on [REDACTED] should be addressed as the Agency is aware of one article that [REDACTED] was found in [REDACTED] following use of a chlorine disinfectant [REDACTED]).

Elaborate on the good management practices that potentially minimize the conditions that give rise to [REDACTED] infections – but also on the reality of being able to eliminate all such conditions that give rise to the growth of [REDACTED] a (e.g., [REDACTED]).

New information on the sources of the pathogenic forms of [REDACTED] on [REDACTED] and in the environment in general would also be very useful. The Agency is aware of only two articles in which attempts were made to identify the sources of [REDACTED] with and without [REDACTED] ). Articles attempting to find the sources of infection on a [REDACTED] or from environmental matrices prior to the concept of the [REDACTED] are of limited value.

8. *Describe whether and how [REDACTED] management practices in managing [REDACTED] caused by [REDACTED] have changed in recent decades and whether these changes have decreased or increased incidences of [REDACTED] from [REDACTED].*

This information would be valuable if available and supported by credible data.

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The most valuable question to ask your expert to respond to:

9. Could increased exposure to [REDACTED] by [REDACTED] potentially result in increased incidence of [REDACTED] ?